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(54) Title: A MEDICAL DEVICE

(57) Abstract: At least part of the support (3) for an embolic protection filter is of a multifilament wire construction. The support (3) comprises Nitinol wires (21) wound in a spiral around a single radiopaque wire (22), the radiopaque wire (22) being located substantially along the axis of bending of the support (3). During bending of the support (3), for example upon movement of the support (3) to the expanded configuration, each wire (21, 22) bends independently of the other wires. As a result, the force required to bend the multifilament support (3) is minimised, and thus the filter (1) achieves enhanced trackability during transport through a tortuous vasculature, such as in coronary applications. Because the Nitinol wires (21) are wound in a spiral around the radiopaque wire (22), this configuration acts to decrease the bending stresses induced in each wire (21, 22) upon bending. The radiopaque wire (22) provides visualisation for a clinician during transport of the filter (1) through a vasculature and deployment of the filter (1) in the vasculature. Because the radiopaque wire (22) is located along the neutral axis of the support (3), the forces required to plastically deform the radiopaque wire (22) as the support (3) moves from the collapsed configuration to the expanded configuration, upon deployment of the filter (1), are minimised. In this way the dampening effect of the radiopaque material is minimised.

"A Medical Device"

Introduction

This invention relates to a medical device for transport through a body passageway and deployment in a body, in particular it relates to an intravascular medical device, such as an embolic protection filter.

It is known to transport an embolic protection filter through a vasculature in a collapsed configuration, and to subsequently deploy the filter at a desired site in the vasculature to an expanded configuration.

However, known filters suffer from the disadvantage that it is generally difficult to transport the collapsed filter through a vasculature, especially in the case of tortuous vasculature, such as in coronary applications, due to low filter trackability.

This invention is aimed at overcoming at least some of the problems associates with known medical devices, and in particular at improving trackability.

Statements of Invention

According to the invention, there is provided a medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

at least part of the support being of a multifilament wire construction.

In the multifilament wire construction of the invention, each filament bends independently of the other filaments. Correspondingly, the overall force required to bend the support is a summation of the forces required to bend each filament. Because the force required to bend a wire is proportional to the fourth power of the diameter of the wire, the overall force required to bend the multifilament support is much less than the force which would be required to bend a single wire with the same overall diameter as the multifilament support.

In this manner, the medical device of the invention achieves enhanced trackability during transport through even tortuous body passageways, while ensuring the medical device is moved by the support from the collapsed configuration to the expanded configuration upon deployment in the body.

The multifilament wire construction also provides the medical device with greater deformability in the expanded configuration. This enables the medical device to adapt to the particular characteristics of the body passageway in which it is deployed.

In one embodiment of the invention at least one filament is wound around at least one other filament. By winding the filament, the bending stress induced in the filament is reduced. Preferably at least some of the filaments are braided together.

In a particularly preferred embodiment at least one filament is of a radiopaque material. The radiopaque nature of the filament provides visualisation of the medical device during transport through and deployment in a body. The radiopaque filament is ideally located substantially along the neutral axis of bending of the support.

In another case at least one filament may comprise a radiopaque core embedded within the filament.

In a further embodiment of the invention the support comprises a jacket around the filaments. The jacket helps to maintain the structure of the multifilament wire construction intact and ensure the filaments move in a co-ordinated manner. Preferably the filaments are embedded within the jacket. Ideally the jacket is at least partially of a radiopaque material. The jacket may be at least partially of a polymeric material.

Desirably the support is of the multifilament wire construction at a point of high curvature in the expanded support.

The device is preferably an intravascular medical device for transport through a vasculature and deployment in a vasculature. Ideally the device is an embolic protection filter. Most preferably the filter has an inlet end and an outlet end, the inlet end having one or more inlet openings sized to allow blood and embolic material enter the filter, and the outlet end having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter.

In a preferred case the filter comprises a filter body supported by the support, and the inlet openings and the outlet openings are provided in the filter body to retain undesired embolic material within the filter body. The filaments may define a mesh. Ideally the inlet openings and the outlet openings are provided by openings through the mesh.

In a further preferred embodiment the support extends proximally of the inlet end. Ideally the support comprises a tether.

In one aspect the invention provides an embolic protection filter having a collapsed configuration for transport through a vasculature, and an expanded configuration for deployment in the vasculature, the filter comprising a support movable from the

collapsed configuration to the expanded configuration, at least portion of the support being of a multifilament wire construction and at least one of the filaments is radiopaque.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings in which:–

Fig. 1 is a side view of a medical device according to the invention;

Fig. 2 is a perspective view of a support of the device of Fig. 1;

Fig. 3 is a perspective view of the support of Fig. 2 in use;

Figs. 4 to 6 are perspective views of supports of other medical devices according to the invention;

Fig. 7 is a perspective view of the support of Fig. 6 in use; and

Figs. 8 to 12 are perspective views of supports of further medical devices according to the invention.

Detailed Description

Referring to the drawings, and initially to Fig. 1 to 3 thereof, there is illustrated a medical device according to the invention. In this case, the medical device is an embolic protection filter 1 which has a collapsed configuration for transport through a

vasculature, and an expanded configuration (Fig. 1) for deployment in a vasculature to filter undesired embolic material from the bloodstream flowing through the vasculature.

The filter 1 comprises a filter body 2 supported by a filter support 3. The filter support 3 is in this case mounted around an inner tube 8. The proximal end 9 of the filter support 3 is fixed to the inner tube 8, and the distal end 10 of the filter support 3 is fixed to a sleeve 11 which is slidable over the inner tube 8, so that the filter 1 is movable from the collapsed configuration to the expanded configuration to support the filter body 2 in the expanded configuration, as illustrated in Fig. 1.

As illustrated in Fig. 2, at least part of the support 3 is of a multifilament wire construction. In this case the support 3 comprises seven Nitinol wires 21 wound in a spiral around a single radiopaque wire 22, the radiopaque wire 22 being located substantially along the axis of bending of the support 3. The support 3 has the multifilament wire construction along the entire length of the support 3 in this instance.

During bending of the support 3 (Fig. 3), for example upon movement of the support 3 to the expanded configuration, each wire 21, 22 bends independently of the other wires. As a result, the force required to bend the multifilament support 3 is minimised, and thus the filter 1 achieves enhanced trackability during transport through a tortuous vasculature, such as in coronary applications.

Because the Nitinol wires 21 are wound in a spiral around the radiopaque wire 22, this configuration acts to decrease the bending stresses induced in each wire 21, 22 upon bending (Fig. 3).

The radiopaque wire 22 provides visualisation for a clinician during transport of the filter 1 through a vasculature and deployment of the filter 1 in the vasculature.

Because the radiopaque wire 22 is located along the neutral axis of the support 3, the forces required to plastically deform the radiopaque wire 22 as the support 3 moves from the collapsed configuration to the expanded configuration, upon deployment of the filter 1, are minimised. In this way the dampening effect of the radiopaque material is minimised.

The filter body 2 has an inlet end 4 and an outlet end 5. The inlet end 4 has one or more, and in this case two, large inlet openings 6 which are sized to allow blood and embolic material enter the filter body 2. The outlet end 5 has a plurality of small outlet openings 7 which are sized to allow through passage of blood but to retain undesired embolic material within the filter body 2. In this way, the filter 1 captures and safely retains any undesired embolic material in the blood stream within the filter body 2 while facilitating continued flow of blood through the vascular system, which could otherwise have potentially catastrophic results.

In the expanded configuration, the filter body 2 is supported by the filter support 3 so as to maximise the internal volume of the filter body 2 to capture and safely retain as much embolic material as possible.

The filter body 2 may be of an oriented polymeric material, as described in International patent application No. PCT/IE01/00087, the relevant contents of which are incorporated herein by reference.

The inner tube 8 has a guidewire lumen 12 therethrough for passing the filter 1 over a guidewire.

In use, a guidewire is introduced into and advanced through a vasculature until the guidewire crossed a desired treatment location. A delivery catheter is then used to deliver the embolic protection filter 1 through the vasculature over the guidewire, the

filter 1 being housed within a distal pod of the delivery catheter in the collapsed configuration.

The filter 1 may, in one case, be loaded into a delivery catheter as described in International patent applications Nos. PCT/IE01/00052 and PCT/IE01/00053, the relevant contents of which are incorporated herein by reference.

When the distal pod has been advanced to a desired site distal to the treatment location, the pod is moved proximally relative to an inner pusher to deploy the filter 1 out of the pod into the expanded configuration, as described in further detail in International patent applications Nos. PCT/IE01/00052 and PCT/IE01/00053. After complete deployment of the filter 1, the delivery catheter is withdrawn from the vasculature.

An interventional procedure is then carried out at the treatment location. A range of procedures are possible such as a stenting procedure using a self-expanding stent, a balloon angioplasty procedure, a balloon-expandable stenting procedure, an atherectomy procedure, a lysis. Any embolic material generated during the interventional procedure is captured and safely retained in the deployed filter 1. After completion of the interventional procedure, a retrieval catheter is introduced into the vasculature, and advanced through the vasculature until the treatment location has been crossed. The filter 1 is then collapsed and retrieved into the retrieval catheter and with it the captured embolic material. When the filter 1 has been fully collapsed and retrieved into the retrieval catheter, the retrieval catheter with the collapsed filter 1 and retained emboli therein are withdrawn from the vasculature. In this way, the filter 1 may be used to capture and safely remove any embolic material which has been generated during the interventional procedure.

Fig. 4 illustrates a support 30 of another embolic protection filter according to the invention. In this case, the support 30 comprises two radiopaque wires 31 around which are wound in a spiral a plurality of Nitinol wires 32.

A support 35 of a further embolic protection filter according to the invention is illustrated in Fig. 5. The Nitinol wires 36 and the radiopaque wire 37 are braided together to form the multifilament wire support 35.

Referring to Figs. 6 and 7 there is illustrated a support 40 of another embolic protection filter according to the invention. The support comprises a single radiopaque wire 42 which extends substantially longitudinally, and a single Nitinol wire 41 which is wrapped around the radiopaque wire 42 in a coil. As illustrated in Fig. 7, the bending stress induced in the Nitinol wire 41 upon bending is substantially less than the bending stresses induced in a solid wire bent through the same angle.

A support 45 of another embolic protection filter is illustrated in Fig. 8. In this case, a single Nitinol wire 47 extends substantially longitudinally, and a single radiopaque wire 46 is wrapped around the Nitinol wire 47 in a coil.

Fig. 9 illustrated part of a support 50 of another embolic protection filter according to the invention. The support 50 is of a multifilament wire construction, and comprises two or more Nitinol wires 51. The support 50 does not have any radiopaque wire filaments, instead radiopacity is achieved by a radiopaque core 52 embedded within at least one of the Nitinol wires 51.

The radiopaque core 52 is located substantially along the neutral axis of the Nitinol wire 51, and thus the force required to plastically deform the radiopaque core 52 during movement of the support 50 from the collapsed configuration to the expanded configuration is minimised, and the dampening effect of the radiopaque material is minimised.

Any suitable radiopaque material may be used for the radiopaque wire(s) 22, 31, 37, 42, 46 or the radiopaque core 52, such as gold, platinum, platinum iridium.

The support wire(s) 21, 32, 41, 47, 51 may be of any suitable superelastic material, or alternatively of a high strength material, such as stainless steel.

Referring to Fig. 10, there is illustrated a support 60 of another embolic protection filter according to the invention, which is similar to the support 3 of Figs. 1 to 3.

In this case, the support 60 comprises a jacket 63 of a polymeric material around the multifilament wires 61, 62. The Nitinol wires 61 and the radiopaque wire 62 are embedded within the polymeric jacket 63. A variety of manufacturing procedures, such as overmoulding, heat-shrinking, dipping, spraying, painting, depositing may be used to fabricate the wires 61, 67 embedded within the jacket 63. The jacket 63 acts to maintain the structure of the multifilament wire construction intact, and ensures that the wires 61, 62 move in a co-ordinated manner.

Fig. 11 illustrates a support 70 of another embolic protection filter according to the invention, which is similar to the support 60 of Fig. 10. In this case the support 70 comprises five Nitinol wires 71 wound together in a spiral without any radiopaque wire filaments. A radiopaque filter, such as tungsten, bismuth subcarbonate, barium sulphate, may be loaded into the polymeric jacket 72 to achieve visualisation.

It will be appreciated that a jacket may be used with any of support structures described previously with reference to Figs. 1 to 9. For example, Fig. 12 illustrates a support 80 of a further embolic protection filter, which is similar to the support 35 of Fig. 5. In this case the Nitinol wires 82 and the radiopaque wire 81 are braided together and embedded in the polymeric jacket 83.

It will be appreciated that the multifilament wire construction may extend only partially along the support. In one case, the support may only be of multifilament wire construction at point(s) which experience high curvature when the filter is in the expanded configuration.

In another embodiment of the invention, the embolic protection filter comprises a filter support only without a separate filter body. The wire filaments of the filter support define a mesh, and the inlet openings of the filter and the outlet openings of the filter are provided by openings through the filament mesh.

In this manner, the filter captures and safely retains any undesired embolic material in the blood stream within the filter while facilitating continued flow of blood through the vascular system. Emboli are thus prevented from flowing downstream through the vascular system.

The multifilament support may extend proximally of the inlet end of the embolic protection filter in the form of a tether arm. The tether facilitates greater control of the filter position in the vasculature, in particular during deployment of the filter.

The tether may be attached to the guidewire or may extend proximally through the vasculature for external control of the filter by the clinician.

The invention has been described in detail with regard to an embolic protection filter, however it will be appreciated that the multifilament wire construction is suitable for use with a support for any type of medical device.

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

Claims

1. An embolic protection filter having a collapsed configuration for transport through a vasculature, and an expanded configuration for deployment in the vasculature, the filter comprising a support movable from the collapsed configuration to the expanded configuration, at least portion of the support being of a multifilament wire construction and at least one of the filaments is radiopaque.

2. A device as claimed in claim 1 wherein at least one filament is wound around at least one other filament.

3. A device as claimed in claim 2 wherein at least some of the filaments are braided together.

4. A device as claimed in any preceding claim wherein the radiopaque filament is located substantially along the neutral axis of bending of the support.

5. A device as claimed in any of claims 1 to 4 wherein the radiopaque filament comprises a radiopaque core embedded within the filament.

6. A device as claimed in any preceding claim wherein the support comprises a jacket for the filaments.

7. A device as claimed in claim 6 wherein the filaments are embedded within the jacket.

8. A device as claimed in claim 6 or 7 wherein the jacket is at least partially of a radiopaque material.

9. A device as claimed in any of claims 6 to 8 wherein the jacket is at least partially of a polymeric material.

10. A device as claimed in any preceding claim wherein the support is of the multifilament wire construction at a point of high curvature in the expanded support.

11. A device as claimed in any preceding claim wherein the filter has an inlet end and an outlet end, the inlet end having one or more inlet openings sized to allow blood and embolic material enter the filter, and the outlet end having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter.

12. A device as claimed in claim 11 wherein the filter comprises a filter body supported by the support, and the inlet openings and the outlet openings are provided in the filter body to retain undesired embolic material within the filter body.

13. A device as claimed in claim 11 or 12 wherein the filaments define a mesh.

14. A device as claimed in claim 13 wherein the inlet openings and the outlet openings are provided by openings through the mesh.

15. A device as claimed in any preceding claim wherein the support comprises a tether.

16. A medical device substantially as hereinbefore described with reference to the accompanying drawings.

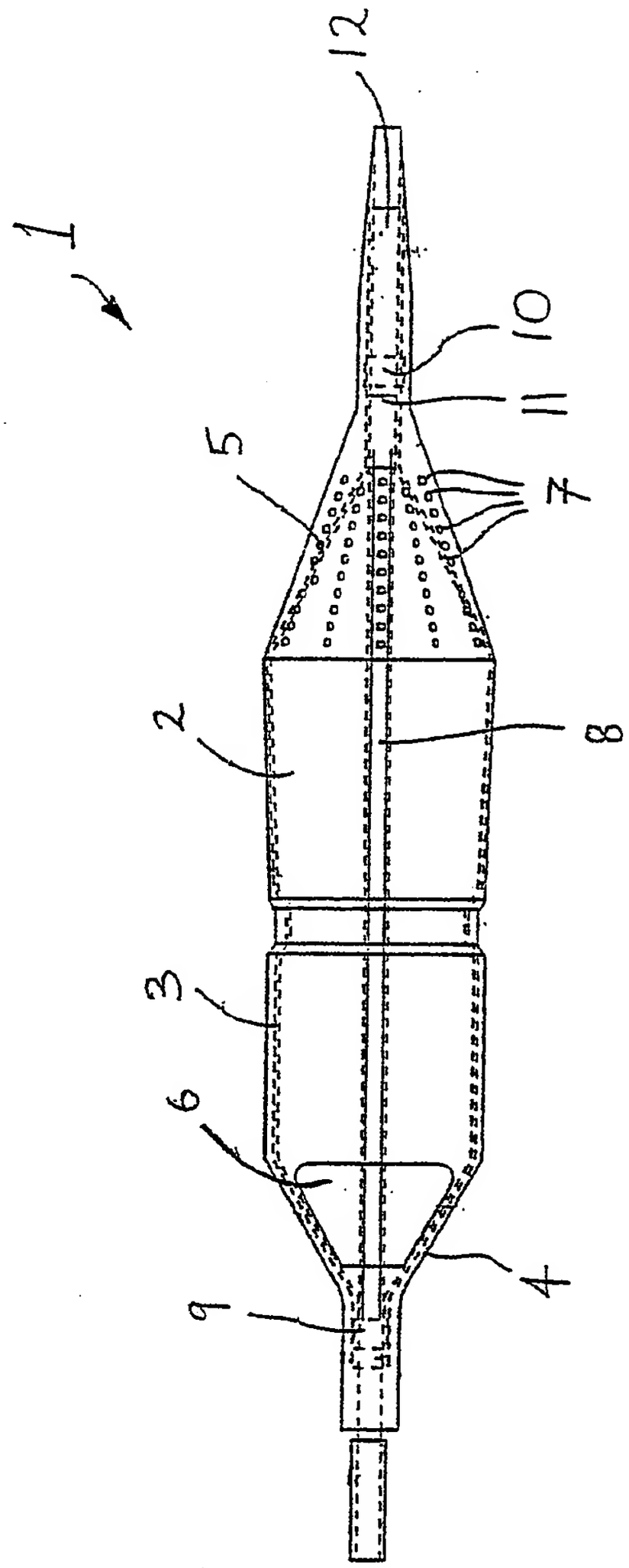

FIG. 1

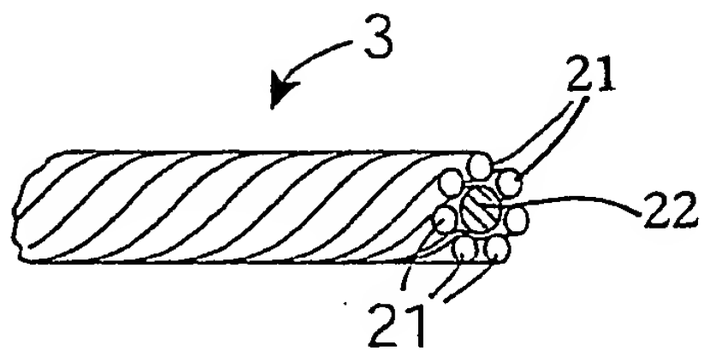

FIG. 2

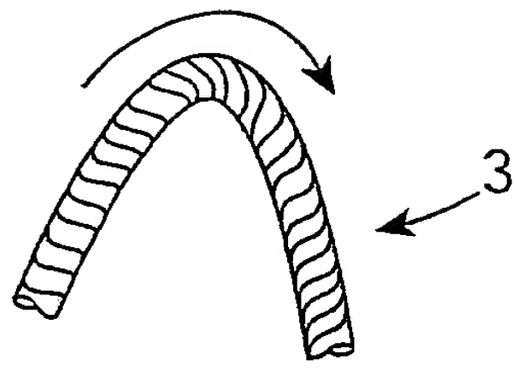

FIG. 3

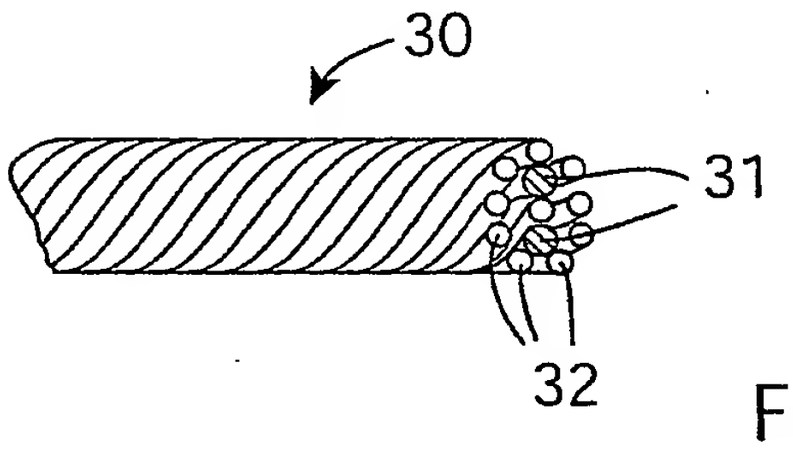

FIG. 4

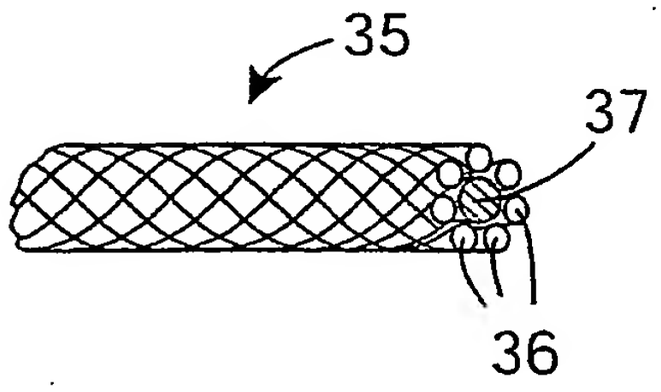

FIG. 5

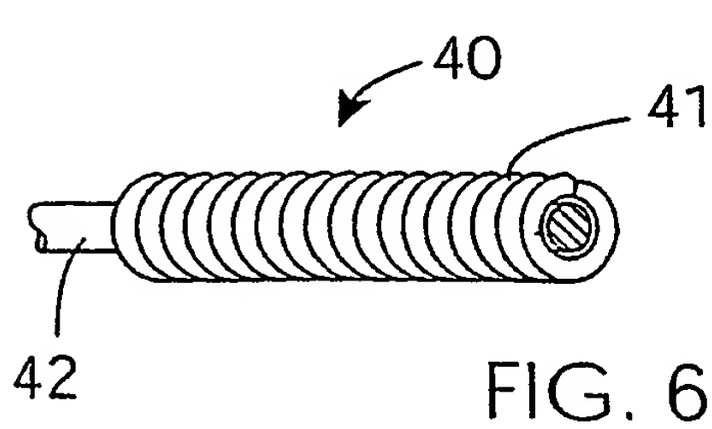

FIG. 6

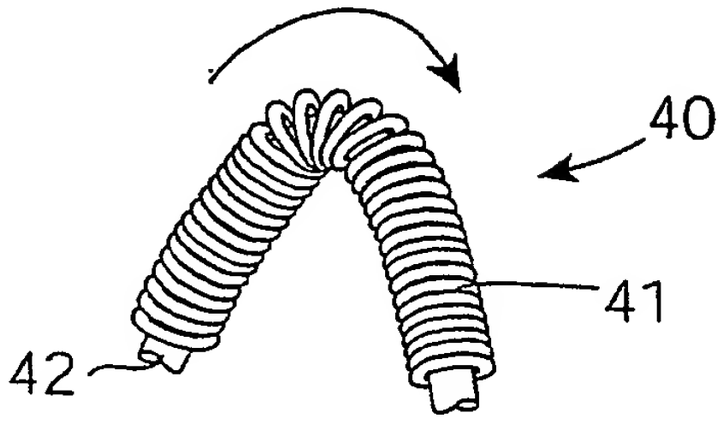

FIG. 7

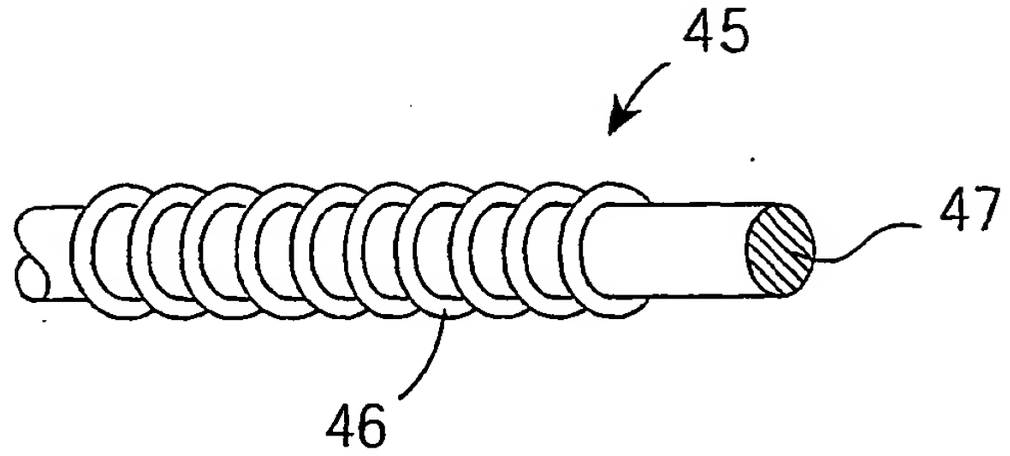

FIG. 8

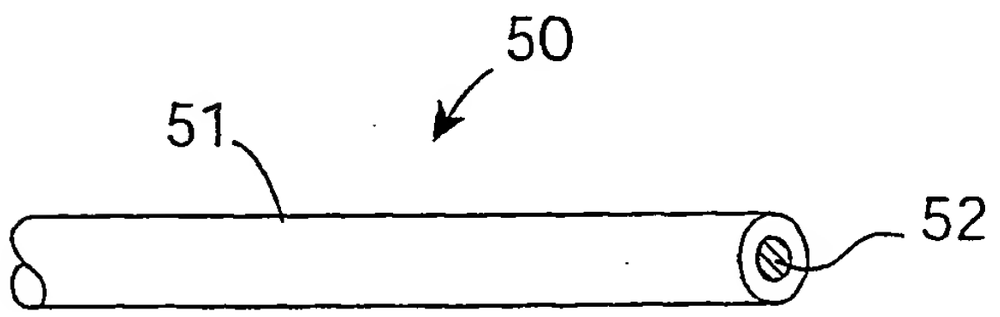

FIG. 9

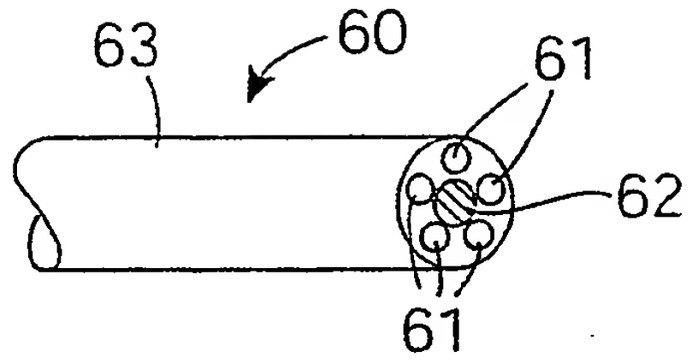

FIG. 10

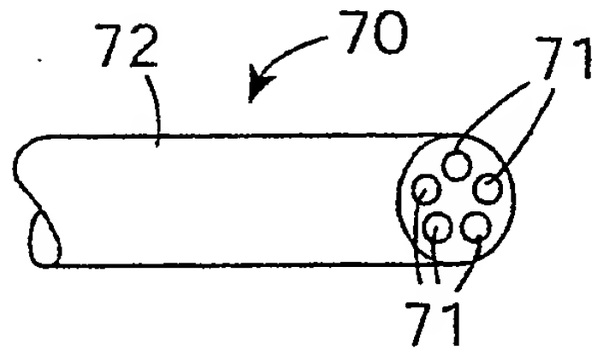

FIG. 11

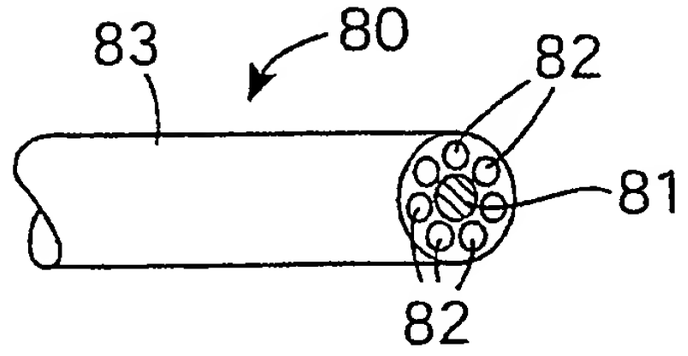

FIG. 12